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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,022 11/24/98 DE FLORA

S P8903-8035

HM12/0317  
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EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

03/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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**Advisory Action**Application No.  
**09/125,022**

Applicant(s)

**De Flora et al.**Examiner  
**Howard Owens**Group Art Unit  
**1623****THE PERIOD FOR RESPONSE:** [check only a) or b)]

- a) ☐ expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Feb 4, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
- ☐ they raise new issues that would require further consideration and/or search. (See note below).
  - ☐ they raise the issue of new matter. (See note below).
  - ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See p.3, lines 2-10 of examiner's rejection of claims 10-12 in the office action mailed 8/4/99.

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☐ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: \_\_\_\_\_

Claims objected to: \_\_\_\_\_

Claims rejected: 13-15

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Other

**JAMES O. WILSON**  
GROUP 1600

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*Detailed Action*

Applicant's amendment A filed 6-9-99 has been received and entered into the record.

Claims 1 - 9 have been canceled. Therefore, only claims 10 - 12 are pending in the case.

All 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

Claims 10 - 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers, Jr. et al. or Doroshow et al. or Meyers et al. or Freeman et al. for the reasons already of record on pages 2 - 4 of the Office action mailed 2-25-99.

The claims are directed to a method for inhibiting cancer metastasis formation in a host comprising the administration of a synergistically effective amount of N-acetyl-cysteine and doxorubicin. Claim 11 specifies that the dosage of N-acetylcysteine be between 100 mg and 6g/day. Claim 12 requires that the doxorubicin be administered in an amount of between 1 and 50 mg per dose.

Each of above references discloses the use of doxorubicin and N-acetylcysteine in the treatment of cancer in the dosage ranges that overlap with applicant's ranges. Unlike the applicant, these references use N-acetylcysteine to reduce the cardiotoxicity of the doxorubicin. However, because the dosage ranges of both doxorubicin and N-acetylcysteine claimed by applicant and used in the prior art overlap, the instantly claimed method for inhibiting cancer metastasis formation is inherent in the prior art method for treating cancer comprising administering doxorubicin and N-acetylcysteine, even though the N-acetylcysteine is being used

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to prevent cardiotoxicity of the doxorubicin.

Another way to understand the inherency of applicant's invention is to grasp the unsolvable nature of the infringement problem applicant would encounter if, in fact, he were awarded a patent to claims 10 - 12. How could the applicant determine if his patent were being infringed by persons who were using doxorubicin and N-acetylcysteine to treat cancer in a patient using the same dosages as applicant's claims? Since the actual physical steps of the potential infringer and those of applicant's claims are indistinguishable, the only way to know if there were, in fact, infringement, would be to discern the mental processes of the person performing the steps. When the only difference between a prior art process and that of a claimed method is the state of mind of the person performing the task, then the prior art process must inherently meet the limitations of the instant claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Information Disclosure Statement***

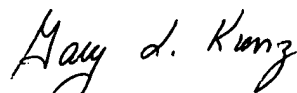
**The references which have been lined through in applicant's PTO Form 1449 filed 2-18-99 were already included on the PTO Form-892 mailed with the first Office action.**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, a supervisor--Cecilia Tsang (703 308-0254) or Gary Jones (703) 308-1152) may be reached. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200